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## A. 510(k) Summary

### 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013081.

**SUBMITTER:**
MedNet Services, Inc.
2855 Anthony Lane, Suite B-10
St. Anthony, MN 55418
Phone: 612-788-6228
Fax: 612-788-6228

**CONTACT PERSON:** David L. Mathews
**TITLE:** President

**DATE PREPARED:** September 11, 2001

**TRADE NAME:** MEDSTAR™ 150

**COMMON NAME:** Powered Muscle Stimulator (89IPF)

**CLASSIFICATION:** 21 CFR 890.5850, Powered Muscle Stimulator Class II

**PRODUCT CODE:** IPF, LIH

**PREDICATE DEVICE (S):** 4000+ Interferential Powered Muscle Stimulator, K950783

**DEVICE DESCRIPTION:** The MEDSTAR 150 is a DC battery powered device that generates small pulses of electrical current. These small pulses of electrical current are delivered through lead cables to electrodes placed on the skin. These electrical pulses pass through the skin and activate underlying nerves and muscle.

**INTENDED USE:** Interferential Stimulation is used under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions to relive pain. When used for pain relief, the standard indications for use are:

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- Symptomatic relief and management of chronic pain and/or
- an adjunctive treatment in the management of post surgical and posttraumatic acute pain.

When used for neuromuscular stimulation, the standard indications for use are:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
- Maintaining or increasing rang of motion

**FUNCTIONAL SAFETY TESTING:**

Was performed with a signal generator voltmeter, 20 ohm resistor, and alligator clip wires. The signal generator was set to 1000 Hz and $V_1$ was set at approximately 2 volts. The voltage drop across the electrodes ($V_2$) was measured and the impedance of the electrodes calculation is as follows:

Impedance (Z) = $V_2/V_1$ x R
Where $V_2$ and $V_1$ are the voltage meter readings.

*Refer to section 6 for further details.*

**CONCLUSION:**

The MEDSTAR 150 is substantially equivalent to 4000+ Interferential Powered Muscle Stimulator in intended use, design and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

Mr. David L. Mathews
President
MedNet Services, Inc.
2855 Anthony Lane, Suite B-10
St. Anthony, Minnesota 55418

Re: K013081
Trade/Device Name: MEDSTAR™ 150 Interferential
and Powered Muscle Stimulator
Regulation Number: 890.5850 and unclassified
Regulation Name: Powered muscle stimulator and Interferential current therapy
Regulatory Class: II
Product Code: IPF, LIH
Dated: September 11, 23001
Received: September 14, 2001

Dear Mr. Mathews:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications For Use Page

510(k) Number (if known): Not yet assigned.

Device Name:
MEDSTAR 150

Indications For Use:
The MEDSTAR 150 should only be used under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions to relive pain. When used for pain relief, the standard indications for use are:

- symptomatic relief and management of chronic pain and/or
- an adjunctive treatment in the management of post surgical and posttraumatic acute pain.

When used for neuromuscular stimulation, the standard indications for use are:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
- Maintaining or increasing rang of motion

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of Ge... ...ve
and Neurolog... ...

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